

REMARKS

By this amendment, claims 1 and 9 and the specification are revised to place this application in condition for allowance. Currently, claims 1-18 are before the Examiner for consideration on their merits.

In the outstanding Office Action, the Examiner has raised a number of issues, which are dealt with under their respective headings.

CLAIM OBJECTIONS

First, the Examiner objects to the use of a carrier material in claim 3 and a skin enhanced in claims 10-18 on the grounds that these two materials are one in the same. In fact, the carrier material and skin enhancer are not synonymous terms. The carrier, which is obviously an optional ingredient since it is not required in claim 1, acts as a vehicle for the active compound until the composition made up of the carrier and active compound contacts the skin and the active compound is absorbed into the skin.

The skin enhancer, identified as a skin penetration enhancer in the specification, on the other hand, is an optional ingredient that is intended to enhance the absorption of the active compound through the skin.

Applicants submit that there is nothing unclear about the description of the skin enhancer on page 5. However, in order to maintain the distinction between the carrier and the skin enhancer, the specification has been appropriately revised and this revision should remove any further objection in this regard. Also, this change does not raise an issue of new matter since it is consistent with the description found

on the last paragraph of page 1 of the specification.

35 U.S.C. § 112, FIRST PARAGRAPH

In the Office Action, the Examiner alleges that claim 1 does not comply with the written description requirement.

Prior to addressing this issue, Applicants wish to further explain the invention and particularly the use of the term “form” in an effort to overcome this rejection. One aspect of the basic invention is the combination of the condom, lubricant and one of (1) an active compound that could be applied directly to a condom without any other ingredients; or (2) the active compound that is part of or within a composition and the composition is applied to the condom. Another aspect of the invention including either of these scenarios is that the active compound as it is described in claim 1 is immiscible with the condom lubricants. In (1), the direct application of the active compound is characterized by using the term “form.” That is, the active compound is in a form and this form is immiscible with the condom lubricant. For (2), the active compound is made part of or within a composition and it is this composition that is immiscible with the condom lubricant.

It should also be noted that the original disclosure did include an embodiment wherein the active compound was dissolved in the lubricant. However, Applicant has opted to claim the other embodiment of the invention which is directed to (1) and (2) described above, i.e., wherein the form of the active compound or the composition containing the active compound are immiscible with the condom lubricant.

The fact that two embodiments were originally described may be contributing

to the confusion as to whether claim 1 is supported by the specification. However, the embodiment wherein (1) or (2) are immiscible with the lubricant is clearly stated at the bottom three lines of page 1 of the specification.

In order to make this aspect of the invention more clear, the last paragraph on page 1 of the application is revised to remove any confusion between the two embodiments originally disclosed and to be consistent with the presently-claimed embodiment.

In conjunction with this change, claim 1 is also revised to make it more clear as to what is being claimed with respect to the combination of the condom and its lubricant. The claim is now better described in the alternative as a form of the active compound or the active compound within a composition with each being immiscible in the lubricant.

In light of the changes to claim 1 and the specification as well as the explanation given above, , it is submitted that claim 1 as proposed is fully supported by the original disclosure and it does not violate 35 U.S.C. § 112, first paragraph.

Secondly, Applicant takes issue with the interpretation of claim 1 that the lubricant is only associated with the second scenario identified in the rejection. A fair reading of the specification shows that the condom is coated with a lubricant, see page 1, the last paragraph thereof. This is an underlying limitation of claim 1 and the wrinkle provided by the invention is the presence of the active compound, whether in a form or within a composition that is immiscible with the lubricant. The Examiner's interpretation that the specification only supports the embodiment that the vasodilator is dissolved in the lubricant therefore it must be miscible with the

lubricant ignores the other embodiment that is explicitly described and presently claimed, see the last paragraph on page 1.

Therefore, claim 1 does not run afoul of the written description requirement and the rejection in this regard must be withdrawn.

The rejection of claim 9 is noted. It is believed that this rejection is overcome by removing the reference to layer or coating therein.

Concerning the use of the term “form”, it is submitted that the use of this term is not a fatal error in enablement. A fair reading of the specification by one of skill in the art would understand the invention as it has been described above. That is, the active compound is either directly applied to the condom or applied as part of a composition. One of skill in the art would understand that the “form” of the active compound alone to merely refer to the form of the active compound that is directly applied to the condom. The compound must have some form for its application and that is all Applicant is intending to mean in using this term to describe this embodiment of the invention. Therefore, describing the active compound as a form for application is an enabling disclosure and the rejection in this regard should be withdrawn.

PRIOR ART REJECTION

The Examiner rejects the claims based on the combination of Crosby and United States Patent No. 6,840,244 to Kemp.

Kemp is not prior art against the application and the rejection must be withdrawn for this reason. First of all, the Kemp patent is only valid under 35 U.S.C.

§ 102(e)/103 since it was issued after the filing date of the instant application.

Moreover, Kemp is disqualified as prior art under 35 U.S.C. § 103(c). In this regard, the following statement is provided in order to demonstrate that the instant application is not prior art.

The undersigned states that the application and the Kemp reference were, at the time that the invention was made, owned by the same person, i.e., Futura Medical Developments Limited.

This statement is sufficient to meet the requirement of 35 U.S.C. § 103(c). Further, because of the common ownership of this application and Kemp at the time of the invention, Kemp is not valid prior art against the claims. With Kemp removed from the rejection, the rejection fails since the Examiner has implicitly admitted that Crosby alone is not sufficient to establish a *prima facie* case of obviousness. Therefore, the rejection must be withdrawn.

SUMMARY

In light of the changes to the claims and the specification, the explanations regarding the invention, and the statement regarding common ownership between Kemp and the application at the time the invention was made, all issues raised in the outstanding Office Action have been addressed and resolved in favor of Applicant.

Accordingly, the Examiner is requested to examine this application in light of this response and pass all claims onto issuance.

If the Examiner believes that an interview would be helpful in expediting the allowance of this application, the Examiner is requested to telephone the

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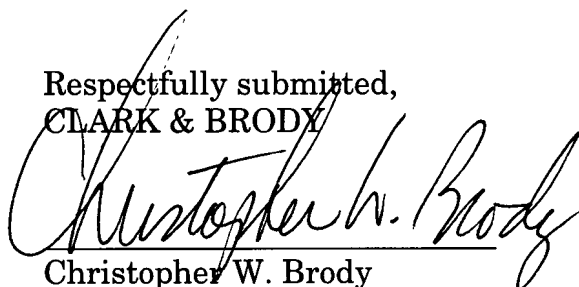
undersigned at 202-835-1753.

The above constitutes a complete response to all issues raised in the Office
Action dated August 21, 2007.

Again, reconsideration and allowance of this application is respectfully
requested.

Please charge any fee deficiency or credit any overpayment to Deposit
Account No. 50-1088.

Respectfully submitted,
CLARK & BRODY

A handwritten signature in cursive script, reading "Christopher W. Brody", written over a horizontal line.

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